Dear Panel Member,

Thank you for agreeing to attend the June 2-3, 2004 meeting of the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee. You will be taking part in a vote to recommend or not to recommend approval of the premarket application (PMA) for the Charité Artificial Disc.

We are providing you with a package of information to assist you in making your recommendation.

Within this binder, we have included memoranda from several FDA reviewers, as well as a list of questions we would like for you to consider. Tab 5 contains the first set of information provided by the sponsor of this PMA:

Tab 1 – Preclinical Review Memo
Tab 2 – Clinical Review Memo
Tab 3 – Statistical Review Memo
Tab 4 – Questions for Consideration
Tab 5 – Preclinical Testing

The remaining five white binders contain additional information from the sponsor of this PMA:

Binder 2 – Wear Debris Testing and Neurotoxicity Evaluation of UHMWPE Particulate
Binder 3 – Summary of Clinical Data and Statistical Analyses
Binder 4 – Statistical Tables
Binder 5 – Statistical Tables (Charité subjects only)
Binder 6 – Clinical Protocols, Investigator Information, Bibliography, and Labeling

Please note that additional preclinical and statistical information has been requested of the sponsor; and review of this information is incomplete at this time. A second mail-out with updated reviews and questions will be provided within the next two weeks.

If you have any questions or concerns, then please do not hesitate to contact me via telephone (301-594-2036, x202) or email (smc@cdrh.fda.gov).

Your input is valuable to us. We appreciate your willingness to review this information and look forward to working with you.

Sergio M. de del Castillo
Lead Reviewer
Orthopedic and Rehabilitative Devices Branch
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Office of Device Evaluation
Center for Devices and Radiological Health